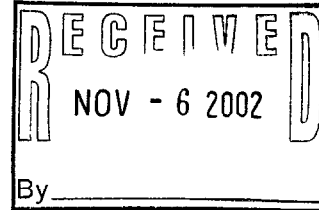


0643 '03 FEB 25 P1:54

16 Sunnyview Drive  
Phoenix, MD 21131  
October 24, 2002

Office of Nutritional Products,  
Labeling and Dietary Supplements (HFS-820)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington, D.C. 20204



Dear Sir or Madam:

Enclosed is the pre-market notification for extract of *Padina pavonica*. If you have any questions regarding this submission, please contact:

Marilyn F. Booker, RN, MS  
16 Sunnyview Drive  
Phoenix, MD 21131  
410-666-5599  
[mbooker@comcast.net](mailto:mbooker@comcast.net)

Sincerely,

A handwritten signature in cursive script that reads "Marilyn F. Booker".

Marilyn F. Booker, RN, MS



## PRE MARKET NOTIFICATION

### Extract of *Padina Pavonica* (EPP)

1. The name and address of the manufacturer of the new dietary ingredient:

Institute of Benthique Algae Limited  
Unite F 24 Mosta Technopark  
Valletta Road  
Mosta MST 09  
Malta

The name and address of the importer of the new dietary ingredient:

ExtractsPlus, Incorporated  
3275 Corporate View Drive  
Vista, CA 92083

The name and address of the encapsulator into dietary supplement:

SSI  
5800 Newton Drive  
Carlsbad, CA 92008

Distributor of the dietary supplement containing new dietary ingredient:

Perfect Equation  
3275 Corporate View Drive  
Vista, CA 92083

Advanced Nutratceutical Concepts  
16 Sunnyview Drive  
Phoenix, MD 21131

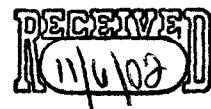
2. Name of the new dietary ingredient

The name of the new dietary ingredient is EPP, an extract of the algae *Padina pavonica*.

3. Description

The description of the new dietary ingredient is as follows: EPP is a natural marine extract from the *Padina pavonica* brown algae; a member of the *Pheophyceae* genus. EPP is an off-white, odorless, fine powder that will be presented for use as a hard gel capsule.

4. Level of the new dietary ingredient in the dietary supplement and conditions and range of use on labeling:



Each hard-gel capsule will contain 200 mg of dry EPP. Adults should take 1 capsule daily orally.

5. Safety:

Local divers handpick the algae throughout the year and deliver the plant to a dedicated laboratory on the Island of Malta. The dry *Padina* is active but activity varies with harvest site, season, depth, water temperature, light, and currents. I.B.A. applies its proprietary extraction process using strict guidelines to assure the safety and efficacy of the product. After extraction, testing by biological titration ensures the efficacy of the final product. Scientists measure calcium fixation by osteoblasts for each batch to ensure consistency and maximum efficacy among batches.

Following European law CEE/67/548 EPP was tested for safety on rats and has been found to be non-toxic and safe for ingestions. See the Chrysalis Report #944/007 of December 30, 1997 (attached as Exhibit A). EPP is non-toxic or mutagenic per Ames II Assay. See the Xenometrix Report #BIO-1097 of October, 1997 (attached as Exhibit B). Toxicity studies in animals show dosages of > 2000 mg/kg without toxicity (attached as Exhibits C and D).

In Asia, *Padina pavonica* is used as a food according to the United Nations Organization for Nutrition and Agriculture (attached as Exhibit E). In addition, for more than a generation, people in Mediterranean countries have eaten these algae.

Based upon the information summarized above and the attached Exhibits, we have concluded that the dietary supplement containing this new dietary ingredient is reasonably expected to be safe.



(M) Ltd.

Institute of Benthique Algae

Unit 1-24, Mosta Technopark, Mosta MST 09, MALTA. Tel: (00356) 438458. Fax: (00356) 419778  
Reg. No. 1444 773 Co. Reg. No. C10704 MALTA

21<sup>st</sup> October 2002

To whom it may concern:

The attached studies use a variety of names and designations for the test materials. These names:

APO G, ADS 11, HPS 3, Padinol Solide ,EPP

We confirm that each of these test materials is a native extract of *Padina pavonica* (EPP) and that these materials were produced using the same process as that used for the production of EPP.

Gilles Gutierrez Ph.D. (Pharmacology)  
President

Directors: C. M. Saliba (Managing), G. Gutierrez, J. Pierresalles